

REMARKS/ARGUMENTS

The Status of the Claims

Claims 1, 3-6, 12-15, 17, 19-23, and 25 are currently pending in this application. Claims 1, 12, 14, and 17 are amended herein to make the language and terminology consistent amongst the claims. Support for such language is replete throughout the specification and claims as filed. For example, support for such changes can be found on, e.g., pages 2, 13, and 19 of the specification, as well as in the claims as originally filed. Claim 20 is amended herein to correct a typographical error. The changes are made without prejudice and are not to be construed as abandonment of any previously claimed subject matter or agreement with any objection or rejection of record. Accordingly, entry of the Amendment is respectfully requested.

The present Office Action objected to claim 20 due to a typographical error, which is corrected herein. The Office Action rejected claims 1, 12, 17, 19, 23, and 25 as allegedly anticipated by Kramer et al. (1995). Also, claims 1, 3-6, 12-15, 17, 19-23, and 25 were rejected as allegedly obvious as to Kramer et al. (1995) in view of Urschel et al. (1990) and Althaus (WO 9303140) and also in view of Unger et al. (EP 731,108) and Unger et al. (1995). Applicants respectfully traverse.

35 U.S.C. §102

Claims 1, 12, 17, 19, 23, and 25 were rejected under 35 U.S.C. §102(b) as allegedly being anticipated by Kramer et al (1995) Nature Medicine, 1(11):1162-1166. Applicants respectfully traverse.

In order for a reference to anticipate an invention, the reference must teach each and every element of the claimed invention. Anticipation requires that "all limitations of the claim are found in the reference, or 'fully met' by it." See Kalman v. Kimberly-Clark Corp., 218 USPQ 781, 789 (Fed. Cir. 1983). Applicants respectfully submit that Kramer does not teach every element of the claims as presented or as amended. As one example, Kramer does not include the required element of a "human or nonhuman primate" as is present in amended claims 1, 12, and 17 (and, thus, in their dependent claims as well). This deficit in Kramer is helpfully highlighted by the Office Action at page 3, which states, in part, that Kramer does not teach "human."

Kramer, thus, cannot act to anticipate the current claims. Because of the foregoing, Applicants believe that Kramer does not anticipate the current claims and respectfully request that the rejections be withdrawn.

35 U.S.C. §103

The current Office Action rejected claims 1, 3-6, 12-15, 17, 19-23, and 25 under 35 U.S.C. §103(a) as allegedly unpatentable over Kramer (1995, above) in view of Urschel et al. (Journal of Comparative Neurology, 1990, 296:114-122) and Althaus (WO 9303140) and further in view of Unger et al. (EP 731,108) and Unger et al. (1995, Poster: 25th Annual Meeting Society for Neuroscience, San Diego, CA, USA November 11-16, 1995). Applicants respectfully traverse.

Three requirements all must be met for a *prima facie* case of obviousness from combined references. First, there must be a motivation to modify the references or combine the teachings to produce the claimed invention. M.P.E.P. §2143.01. Second, there must be a reasonable expectation of success. M.P.E.P. §2143.02. Third, the prior art reference(s) must teach all of the limitations of the claims. M.P.E.P. §2143.03. Furthermore, the teaching or suggestion to combine and the expectation of success must both be found in the prior art and not based upon the disclosure of the Applicants. M.P.E.P. §2142.

Applicants respectfully point out that these requirements have not been met for a *prima facie* showing of obviousness from either combination of references.

For example, the cited references fail to meet *prima facie* obviousness because, e.g., there is no motivation to combine Kramer and either Urschel/Althaus or Unger/Unger. The cited references do not contain a motivation to modify or combine the teachings to produce the current invention, nor does the Office Action point to such a motivation elsewhere. The Office Action alleges that a person would be motivated to combine the references, “because it is well known that cognate specific proteins are preferentially used.” Office Action at page 5. However, even assuming, *arguendo*, that the references mention, e.g., treatment of MS, NGF and myelin, etc., at most such would be an invitation to experiment to see whether a hoped for result may occur, which is not a legitimate basis for establishing obviousness. *See, e.g., Ex Parte Erlich*, 3 USPQ2d 1529 (Fed. Cir. 1988); *In re Geiger*, 2 USPQ2d 1276 (Fed. Cir. 1987); *In Re Dow*, 5 USPQ2d 1529 (Fed. Cir. 1988); and *In Re Eli Lilly & Co.* 14

USPQ2d 1741, 1743 (Fed. Cir. 1990). As the court has repeatedly held, one may not establish motivation by pointing to a passage that invites experimentation to see if something will work. The Office Action has presented no specific instance in the cited references or elsewhere that would constitute a motivation or suggestion to combine the references and, thus, the requirements for *prima facie* obviousness have not been met.

The cited references also fail to present *prima facie* obviousness because there is no reasonable expectation of success, fully achieving the desired invention, in the combined references. Thus, there is no reasonable expectation of success in combining Kramer with Urschel/Althaus or Kramer with Unger/Unger. For example, even if Kramer, *arguendo*, contains statements concerning decreasing demyelination in rodent neurons, there is no expectation of success in combining it with the rat model in Urschel and the porcine/human in Althaus. As pointed out in the specification at page 19,

It is important to recognize that, due to the interspecies differences in the biological effects of growth factors and the differential expression of their specific receptors, information derived from rodent studies may not be applicable to humans.

Such passage highlights the lack of expectation of success for combination of such references.

Furthermore, while again *arguendo*, Kramer might concern decreased demyelination, Althaus focuses on regeneration of myelin, while, Urschel is even further away in that it focuses on showing that removal of NGF affects myelination (not that adding NGF increases myelin). Thus, Kramer, Althaus, and Urschel concern different actions/aspects of myelin and there would be no reasonable expectation of success in combining them.

Similarly, there is no reasonable expectation of success in combining Kramer and Unger/Unger. As with the combination of Kramer and Urschel/Althaus, there is no reasonable expectation of success in combining the rodent data in Kramer with the porcine data in Unger/Unger. Additionally, as explained below, such combination does not present all elements (e.g., "human or nonhuman primate") of the present claims. Furthermore, the

focus of Kramer is different from that of Unger/Unger which concentrate on regeneration of myelin, not demyelination. Thus, there would be no reasonable expectation of success in combining Kramer and Unger/Unger.

Finally, the combinations of Kramer and Urschel/Althaus and Kramer and Unger/Unger do not even present all the elements of all of the current claims. For example, the combination of Kramer and Urschel/Althaus does not provide "optic nerves" (as used in claims 14 and 15) or "interferon γ " (as used in claims 17-25). As another example, Kramer and Unger/Unger do not provide "human or nonhuman primates," etc. as is used by claims 1, 12, 14, and 17 (and their dependents).

In sum, the cited references fail to meet the three required aspects of *prima facie* obviousness and Applicants respectfully request that the rejections be withdrawn.

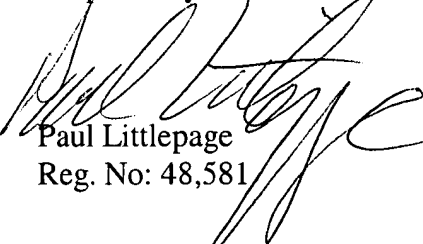
CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If the claims are deemed not to be in condition for allowance after consideration of this Response, a telephone interview with the Examiner is hereby requested. Please telephone the undersigned at (510) 769-3507 to schedule an interview.

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Respectfully submitted,



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- 1) A petition to extend the period of response for 3 months (+one copy);
- 2) A transmittal sheet; and,
- 3) A receipt indication postcard.